CLAIMS

1. (Original) A pharmaceutical formulation comprising:

a first composition comprising a therapeutically effective amount of at least one muscle relaxant; and,

a different second composition comprising a therapeutically effective amount of at least one cyclooxygenase-2 (COX II) inhibitor,

wherein the first composition provides a controlled and/or extended release of the muscle relaxant and the second composition provides a rapid and/or immediate release of the COX II inhibitor.

2. (Original) The pharmaceutical formulation of claim 1, wherein the first composition comprises

(a) a core region comprising an effective amount of the muscle relaxant and

(b) a membrane layer that extends the release of said muscle relaxant, wherein said membrane layer is selected from:

(i) a controlled release coating on said core region;

(ii) a matrix layer, which is integrated with said core region; or

(iii) a combination thereof.

3. (Original) The pharmaceutical formulation of claim 1, which is selected from the group consisting of capsules containing immediate and sustained release granules, capsules containing sustained release granules and one or more immediate release tablets, capsules containing sustained release granules and powder, extended release film or multi-layer coated tablets.

4. (Original) The pharmaceutical formulation of claim 1, wherein each of the first and second composition further comprises at least one pharmaceutical excipient.

5. (Original) The pharmaceutical formulation of claim 1, wherein the first and second compositions are in layered arrangement with respect to one another.

6. (Original) The pharmaceutical formulation of claim 3, wherein the second composition surrounds the first drug composition.

7. (Original) The pharmaceutical formulation of claim 6, wherein the first composition is in contact with the second drug composition.

8. (Original) The pharmaceutical formulation of claim 6, wherein the first drug composition is spaced-away from the second drug composition.

9. (Original) The pharmaceutical formulation of claim 1, wherein the first composition is included in a core and the second composition is included in a coat, of one or more coats, surrounding the core.

10. (Original) The pharmaceutical formulation of claim 1, wherein the first composition is a granulation, the second drug composition is a powder, granulation or compressed tablet and the formulation is a capsule.

11. (Original) The pharmaceutical formulation of claim 1, wherein said muscle relaxant is a alpha-2 adrenergic agonist.

12. (Original) The pharmaceutical formulation of claim 11, wherein the alpha-2 adrenergic agonist is tizanidine and pharmaceutically acceptable salts, isomers, and derivatives thereof.

13. (Original) The pharmaceutical formulation of claim 2, wherein said controlled release coating is comprised of a material selected from the group consisting of a water insoluble wax, a water insoluble cellulose, a water insoluble polymer, and combinations thereof.

14. (Original) The pharmaceutical formulation of claim 13, wherein said water insoluble cellulose is ethyl cellulose.

15. (Original) The pharmaceutical formulation of claim 13, wherein said water insoluble polymer is comprised of an acrylic resin.

16. (Original) The pharmaceutical formulation of claim 15, wherein said acrylic resin is poly(meth)acrylate.

17. (Original) The pharmaceutical formulation of claim 13, wherein said controlled release coating is further comprised of a water soluble polymer.

18. (Original) The pharmaceutical formulation of claim 17, wherein said water soluble polymer is polyvinyl pyrroldine.

19. (Original) The pharmaceutical formulation of claim 1, wherein said controlled release coating is further comprised of a water soluble cellulose.

20. (Original) The pharmaceutical formulation of claim 19, wherein said water soluble cellulose is hydroxypropyl methylcellulose.

21. (Original) The pharmaceutical formulation of claim 19, wherein said water soluble cellulose is hydroxypropyl cellulose.

22. (Original) The pharmaceutical formulation of claim 13, wherein said controlled release coating is further comprised of a hydrophilic pore former.

23. (Original) The pharmaceutical formulation of claim 22, wherein said hydrophilic pore former is sodium chloride.

24. (Original) The pharmaceutical formulation of claim 22, wherein said hydrophilic pore former is mannitol.

25. (Original) The pharmaceutical formulation of claim 13, wherein said controlled release coating is further comprised of a plasticizer.

26. (Original) The pharmaceutical formulation of claim 1, further comprising at least one excipient.

27. (Original) The pharmaceutical formulation of claim 2, wherein said matrix layer is selected from the group consisting of a hydrophilic polymer, a hydrophobic polymer, a hydrophobic wax, a hydrophobic fat, a hydrophobic long-chain fatty acid, a hydrophobic fatty alcohol, esters thereof, ethers thereof and mixtures thereof.

28. (Original) The pharmaceutical formulation of claim 27, wherein said hydrophilic polymer is cellulose ether.

29. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is cellulose ester.

30. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is an acrylic resin.

31. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is ethyl cellulose or a salt, amide or ester thereof.

32. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is hydroxypropyl methylcellulose or a salt, amide or ester thereof.

33. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is hydroxypropylcellulose or a salt, amide or ester thereof.

34. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is hydroxymethylcellulose or a salt, amide or ester thereof.

35. (Original) The pharmaceutical formulation of claim 28, wherein said hydrophilic polymer is poly(meth)acrylic acid or a salt, amide or ester thereof.

36. (Original) The pharmaceutical formulation claim 28, further comprising an excipient selected from the group consisting of a diluent, a retardant, a lubricant, a glidant and mixtures thereof.

37. (Original) The pharmaceutical formulation of claim 36, wherein said excipient is microcrystalline cellulose.

38. (Original) The pharmaceutical formulation of claim 37, wherein said microcrystalline cellulose is Avicel pH-102.

39. (Original) The pharmaceutical formulation of claim 38, wherein the concentration of said Avicel pH-102 is about 20 to about 90 percent.

40. (Original) The pharmaceutical formulation of claim 36, wherein said diluent is lactose.

41. (Original) The pharmaceutical formulation of claim 40, wherein said lactose is selected from the group consisting of hydrous lactose, anhydrous lactose, crystalline lactose, powdered lactose and mixtures thereof.

42. (Original) The pharmaceutical formulation of claim 41, wherein said lactose is direct compression grade.

43. (Original) The pharmaceutical formulation of claim 42, wherein said direct compression grade lactose is comprised of alpha lactose monohydrate and amorphous lactose.

44. (Original) The pharmaceutical formulation as of claim 37, wherein said excipient is anhydrous dibasic calcium phosphate.

45. (Original) The pharmaceutical formulation of claim 44, wherein said excipient further includes a lubricant selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and mixtures thereof.

46. (Original) The pharmaceutical formulation of claim 1, wherein said matrix layer is further comprised of pregelatinized starch.

47. (Original) The pharmaceutical formulation of claim 37, wherein said retardant is a methacrylic acid copolymer.

48. (Original) The pharmaceutical formulation of claim 47, wherein said methacrylic acid copolymer is a polymethacrylate copolymer.

49. (Original) The pharmaceutical formulation of claim 47, wherein said methacrylic acid copolymer is Eudragit RS PO.

50. (Original) The pharmaceutical formulation of claim 47, wherein said methacrylic acid copolymer is Eudragit NE 30D.

51. (Original) The pharmaceutical formulation of claim 49, wherein from about five to about twenty percent of said polymethacrylate copolymer is present in said matrix as dry powder is added to said matrix.

52. (Original) The pharmaceutical formulation of claim 27, wherein said excipient is an ethyl cellulose dispersion.

53. (Original) The pharmaceutical formulation of claim 52, wherein said ethyl cellulose dispersion is present in said matrix at a concentration of about three to about twenty percent.

54. (Original) The pharmaceutical formulation of claim 37, wherein said glidant is colloidal silicon dioxide.

55. (Original) The pharmaceutical formulation of claim 1, wherein said COX II inhibitor is selected from the group consisting of valdecoxib, celicoxib, paracoxib, etoricoxib, MK-0966, NS 398 and mixtures thereof.

56. (Original) The pharmaceutical formulation of claim 1, wherein said muscle relaxant is tizanidine and pharmaceutically acceptable salts, isomers, and derivatives thereof and said COX II inhibitor is valdecoxib.

57. (Original) A method for the treatment or prevention of pain and/or spasticity comprising administering to a subject in need of such treatment or prevention a pharmaceutically effective amount of the pharmaceutical formulation of claim 1.

58. (Original) A method for the treatment or prevention of pain and/or spasticity comprising administering to a subject in need of such treatment or prevention a pharmaceutically effective amount of the formulation of claim 5.

59. (Original) A method for the treatment or prevention of pain and/or spasticity comprising administering to a subject in need of such treatment or prevention a pharmaceutically effective amount of the formulation of claim 55.

60. (Original) A method for the treatment or prevention of pain and/or spasticity comprising administering to a subject in need of such treatment or prevention a pharmaceutically effective amount of the formulation of claim 56.

61. (Original) An orally administrable dosage form containing the pharmaceutical formulation of claim 1, wherein said dosage form provides once daily dosing for therapeutic relief from skeletal muscle spasms.

62. (Original) The dosage form of claim 61, wherein said muscle relaxant is tizanidine and pharmaceutically acceptable salts, isomers, and derivatives thereof.

63. (Original) The dosage form of claim 61, wherein said COX II inhibitor is valdecoxib.

64. (Original) The dosage form of claim 61, wherein said muscle relaxant is tizanidine and pharmaceutically acceptable salts, isomers, and derivatives thereof and said COX II inhibitor is valdecoxib.